Testing of the Guidance on Risk Assessment of Living Modified Organisms

#9

COMPLETE

Collector: BCH website (Website Survey)
Started: Friday, March 28, 2014 3:44:07 PM
Last Modified: Tuesday, April 01, 2014 3:36:25 AM
Time Spent: Over a day

PAGE 1

Q1: **Type of submission:**	Organization

PAGE 2

Q2: Name of the Party:	*Respondent skipped this question*
Q3: Person submitting this questionnaire:	*Respondent skipped this question*
Q4: Institution(s) or organization(s) that participated in the testing:	*Respondent skipped this question*
Q5: Context in which the testing was conducted	*Respondent skipped this question*
Q6: Actual case(s) of risk assessment used in the testing: Note: Please enter the hyperlinks of BCH Risk Assessment Records (e.g. http://bch.cbd.int/database/record.shtml?documentid=104904 and http://bch.cbd.int/database/record.shtml?documentid=104905) or other publicly accessible web pages containing the technical and scientific data of the actual cases of risk assessment used in the testing.	*Respondent skipped this question*
Q7: In what language was the Guidance tested?	*Respondent skipped this question*

PAGE 3

Q8: Name of the other Government:	*Respondent skipped this question*
Q9: Person submitting this questionnaire:	*Respondent skipped this question*
Q10: Institution(s) or organization(s) that participated in the testing:	*Respondent skipped this question*
Q11: Context in which the testing was conducted	*Respondent skipped this question*
Q12: Actual case(s) of risk assessment used in the testing: Note: Please enter the hyperlinks of BCH Risk Assessment Records (e.g. http://bch.cbd.int/database/record.shtml?documentid=104904 and http://bch.cbd.int/database/record.shtml?documentid=104905) or other publicly accessible web pages containing the technical and scientific data of the actual cases of risk assessment used in the testing.	*Respondent skipped this question*
Q13: In what language was the Guidance tested?	*Respondent skipped this question*

PAGE 4

Q14: Name of the organization:	Public Research and Regulation Initiative (PRRI)
Q15: Person submitting this questionnaire:	
Full Name:	Marc Van Montagu
Email Address:	info@prri.net
Q16: Institution(s) or organization(s) that participated in the testing:	Academic institution(s), Non-governmental organization(s)
Q17: Context in which the testing was conducted	Other (please specify) testing was conducted by scientists who are involved in risk assessment and/or in teaching risk assessment

Q18: Actual case(s) of risk assessment used in the testing: Note: Please enter the hyperlinks of BCH Risk Assessment Records (e.g. http://bch.cbd.int/database/record.shtml?documentid=104904 and http://bch.cbd.int/database/record.shtml?documentid=104905) or other publicly accessible web pages containing the technical and scientific data of the actual cases of risk assessment used in the testing.

Risk Assessment 1:	http://bch.cbd.int/database/decisions/

Q19: In what language was the Guidance tested?	English

PAGE 5

Q20: Would you like to submit an evaluation of the following section of the Guidance: Part I: The Roadmap for Risk Assessment	Yes

PAGE 6

Q21: This section of the Guidance is practical.1

(no label)	Disagree

Q22: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:

The Road map is not very practical, because of its very nature and because of the way it is written. The language is very dense and of a 'legal negotiation' type, with often sentences of several lines that are extremely difficult to follow for non native English speakers. Moreover, the way risk assessment is introduced gives the wrong impression that there must always be risks (e.g. language such as "the risk posed by the LMO"). This is underlined by the flow chart which in all cases ends with "consideration of risk management". Further, the text gives the wrong impression that risk assessment is a process with which we have hardly any experience and that is riddled uncertainties. In fact, the detailed elaboration of uncertainty gives the wrong impression that this field is faced with more uncertainties than any other type of risk assessment in the field of biology.
In addition, the text gives the wrong impression that natural phenomena such as out crossing and instability of genotypes or phenotypes is an unusual phenomenon that means risk.
All this is pervasive throughout the document, and cannot be pinpointed to specific lines to be changed. A general clean up would be advisable.

While we very much support the original idea to elaborate on the steps and points to consider in environmental risk assessment as outlined in Annex III and by pointing users to relevant background materials, the way it is done will give the Road Map little practical value, because novice risk assessors will either ignore the dense text or be deterred by the sheer notion of risk assessment.

Q23: This section of the Guidance is useful or has utility.2

(no label)	Disagree

Q24: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:

Although the practical value of the Roadmap for specific cases is very limited, it can – after revision – be quite useful, to further explain the basis of risk assessment, in the same way as in the past an OECD "Preamble" document laid the basis for subsequent specific documents to build on.

Q25: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) Neutral

Q26: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:

While the verbatim quotes of provisions of the Protocol are obviously consistent with the text Protocol, the overall flavour of the documents (e.g. the notion that there must be risks, the disproportionate emphasis on uncertainties and the absence of the notion that this technology is anticipated to have great benefits goes against the background and legal basis of the Protocol, such as:
• Access to and transfer of biotechnology are essential elements to attain the objectives of the CBD (Article 16 CBD)
• Parties agree to promote and advance priority access to the results and benefits arising from biotechnologies (articles 19.1 and 19.2 of the CBD)
• Modern biotechnology has great potential for human well-being (Preamble CPB)

These references should be included and repeated at least frequently as the references to risks and uncertainties.

Q27: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label) Strongly Disagree

Q28: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:

As said, the way risk assessment is introduced gives the impression that there must always be risks (e.g. language such as "the risk posed by the LMO"), that all the details will be needed in every case, and that risk assessment is a process with which we have hardly any experience and that is riddled uncertainties.

To give the Roadmap better perspective and usefulness, it is advisable to include in the Background after the sentence "However, it has been developed based largely on living modified (LM) crop plants because the experience to date with environmental risk assessments of LMOs has been mainly gained from these organisms." (line 182) some further detail about the experience to date, with data from the last 4 decades about the number of risk assessments conducted, the number of field trials conducted, the area over which certain GM crops have been grown, with reference to an Annex with contact points of countries and organisations that have conducted these risks assessments, field trials and commercial planting, as well as the notion that the experience with these decades of risks assessments, field trials and commercial planting does not indicate any verifiable report of adverse affects to human health of teh environment.

Q29: Here you may provide further details to explain your answers in evaluating this section of the Guidance: *Respondent skipped this question*

PAGE 7

Q30: Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LMOs with stacked genes or traits Yes

PAGE 8

Q31: This section of the Guidance is practical.1

(no label) Strongly Disagree

Q32: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:

One of the key paradigms of LMO risk assessment is that it is comparative, i.e. that indentified risks should be considered in the context of the risks posed by the non-modified recipients or parental organisms. To be of practical value for risk assessment, any guidance document should therefore: 1) provide a clear explanation of what happens in nature and with conventional breeding, 2) identify cases that go beyond what happens in nature and with conventional breeding that could give rise to safety questions, and 3) give practical how to address such questions.
This document does nothing of the sort

1) This document does not provide any introduction that places the topic in the context of the fact that organisms are in fact sets of thousands - and often tens of thousands - of 'stacked genes'. Neither does the document explain that it is in fact the aim of every farmer, and therefore of every plant breeder, to have as many useful genes 'stacked' in one plant, e.g. genes for pest and disease resistance, combined with genes for better taste and higher yield, etc etc. In short, the document should start with a 'setting the scene' that stacked genes are a natural phenomenon and a very common result of breeding, and all with interactions between genes and pathways. However, rather than explaining this, the introduction and the entire document give the impression that stacked genes are somehow a rarity and above all that somehow stacked genes are prone to risk. To give just one of many examples that can be found in the text "During cross-breeding, changes may occur to the molecular characteristics of the inserted genes/genetic elements at the insertion site(s) as a result of recombination, mutation and rearrangements.". What it should say is " as with any genes in an organism .....".

2) The document does not give any guidance how to identify cases that go beyond what happens in nature and with conventional breeding that could give rise to safety concerns and that could give rise to safety questions. The document does not make reference to the growing list of literature that indicates that there is in general no scientific justification to look separately at stacked genes if the individual events have already been assessed (e.g. Kok et at: Plants with stacked genetically modified events: to assess or not to assess?, TibTech, 2013.12.001). The document should make this clear and then offer practical guidance how to identify the cases where a separate assessment would be warranted. However, rather than doing this, the document suggests that in all cases stacked genes should be subject to renewed assessment.

3) The document does not give practical guidance how to address particular safety questions that would have arisen from the previous steps in which cases have been identified where a separate assessment would be warranted. However, rather than doing this, the document comes with an endless list of 'points to consider, without explaining in which cases those points would be relevant, how those questions could be answered in a way that is relevant for risk assessment.

Examples of such points are: Level of heterozygosity among the non-modified recipient organisms used to produce the parental LM plants; phenotypic variability among non-modified hybrids produced through crosses between the non-modified recipient organisms; Number of crossings and the use of intermediate stacked LM plants as additional comparators; Phenotypic changes that may indicate underlying changes to any of the transgenes and genetic elements present in the stacked LM plant. Etc etc
On various points, the document does not only provide little to no practical guidance when and how to answer questions, but instead sends the reader in a direction that shows that the authors have very little understanding of the topic itself. For example, the suggestion that the stacking of various insecticidal proteins in an LM plant could result in a faster development of resistance in target organisms has no basis. If anything, the stacking of various insecticidal proteins will delay resistance development.

In short, this section is best retracted.

Q33: This section of the Guidance is useful or has utility.2

(no label) Strongly Disagree

Q34: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:

See explanation under point 17.

Q35: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) Strongly Disagree

Q36: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:

The Protocol requires that risk assessment is scientifically sound and transparent, and conducted in line with the comparative paradigm. As explained above, this document does not do any of this.

There is nothing scientifically sound about suggesting that stacked genes are somehow a rarity and above all that somehow stacked genes are more prone to risk than with crossings happening in nature or with conventional breeding.
There is nothing transparent about listing a blur of points to consider, without indicating in which type of cases those points would be relevant, how those points should be addressed and how the results will be relevant to risk assessment.
Specific line numbers cannot be given, because this problem is pervasive in the entire document.

Q37: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label) Strongly Disagree

Q38: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:

See point 20

Q39: Here you may provide further details to explain your answers in evaluating this section of the Guidance: *Respondent skipped this question*

PAGE 9

Q40: Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LM crops with tolerance to abiotic stress Yes

PAGE 10

Q41: This section of the Guidance is practical.1

(no label) Strongly Disagree

Q42: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:

The Introduction to this sections starts with “there are a number of specific issues that may be of particular importance when assessing the risks of LM plants tolerant to abiotic stresses”, but what then follows throughout the entire section are issues that are not specific to risk assessment of abiotic stress traits.
The resulting document is therefore nothing more than a repetition of the general statements in the RoadMap, e.g: “Some of the issues that could arise from the introduction of LM plants tolerant to abiotic stress into the environment and which may lead to adverse effects include, for example: a) increased selective advantage(s), other than the intended tolerance trait, which may lead to potential adverse effects (e.g., resulting from the introduction of a transcription factor affecting more than one trait); b) increased persistence in agricultural areas and increased invasiveness in natural habitats; c) adverse effects on organisms exposed to the LM plant; and d) adverse consequences of potential gene flow to wild or non-modified relatives”.

None of this is specific to abiotic stress and therefore the document does not provide any useful or practical guidance specific to that topic. This is comes back repeatedly from the points to consider, e.g.: “Does the tolerance trait have the potential to cause an increase of the invasiveness, persistence or weediness of the LM plant that could cause adverse effects to other organisms, food webs or habitats? “.
Or: ” Any intended or unintended change that may lead to selective advantage or disadvantage acquired by the LM plant under other abiotic or biotic stress conditions that could cause adverse effects;“
Or:” it is of particular importance that the assessment of potential adverse effects of LM plants with tolerance to abiotic stress be conducted in relation to the ‘likely potential receiving environment’ of the LM plant under consideration”
Or: ” The likely potential receiving environment where exposure to the LM plant may occur and its characteristics such as information on geographical, climatic and ecological characteristics, including relevant information on biological diversity, centres of origin and centres of genetic diversity”;
None of this is specific to abiotic stress, and none of this provides any practical guidance.
It is striking that the organisers of this testing have asked to apply this guidance to “real cases”. Irrespective of the case taken, none of this guidance is specific enough to help identify in which cases certain points to consider would be relevant, and how those points could be answered.
All this is pervasive throughout the document, and cannot be pinpointed to specific lines to be changed. A general, drastic revision would be appropriate, whereby a clear distinction should be made for guidance in case of releases for confined field trials and guidance for placing on the market.

Q43: This section of the Guidance is useful or has utility.2

(no label) Strongly Disagree

Q44: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:

See above comments

Q45: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) Neutral

Q46: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:

See comments under point 30

Q47: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label) Strongly Disagree

Q48: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:

See comments under point 30

Q49: Here you may provide further details to explain your answers in evaluating this section of the Guidance: *Respondent skipped this question*

PAGE 11

Q50: Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LM mosquitoes No

PAGE 12

Q51: This section of the Guidance is practical.1 *Respondent skipped this question*

Q52: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made: *Respondent skipped this question*

Q53: This section of the Guidance is useful or has utility.2 *Respondent skipped this question*

Q54: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made: *Respondent skipped this question*

Q55: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3 *Respondent skipped this question*

Q56: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made: *Respondent skipped this question*

Q57: This section of the Guidance takes into account past and present experiences with LMOs.4 *Respondent skipped this question*

Q58: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made: *Respondent skipped this question*

Q59: Here you may provide further details to explain your answers in evaluating this section of the Guidance: *Respondent skipped this question*

PAGE 13

Q60: Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LM trees Yes

PAGE 14

Q61: This section of the Guidance is practical.1

(no label) Strongly Disagree

Q62: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:

The same applies here as for the section on abiotic stress tolerance, and here too the resulting document is therefore nothing more than a repetition of the general statements in the Roadmap.
For all of the lengthy discussion in the guidance document there is little real guidance. There is little mention of utilizing our centuries or millennia of experience with non-LM crop plants/trees. We know that some of our current agricultural practices are environmentally unsound and many of our current crop/tree varieties require these practices to sustain their cultivation. To take these practices and non-LM varieties as gold standards seems to preclude the consideration of benefits derived from LMOs.
That is why we must draw on the base of knowledge with non-LM trees to evaluate both the potential risks and benefits. We suggest to consider OECD biology documents in this context one.

Q63: This section of the Guidance is useful or has utility.2

(no label) Disagree

Q64: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:

This section can be useful, but not in the form it is in now.

Q65: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) Neutral

Q66: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made: *Respondent skipped this question*

Q67: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label) Strongly Disagree

Q68: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:

See above

Q69: Here you may provide further details to explain your answers in evaluating this section of the Guidance: *Respondent skipped this question*

PAGE 15

Q70: Would you like to submit an evaluation of the following section of the Guidance: Part III: Monitoring of LMOs Released into the Environment	Yes

PAGE 16

Q71: This section of the Guidance is practical.1

(no label) — Disagree

Q72: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:

The text starts with “Monitoring of LMOs released into the environment may allow the detection, in a timely manner and as early as possible, of changes that may lead to adverse effects”. This is indeed done of the uses of monitoring, but what seems to happen throughout the document is that the texts moves away from “detecting changes” to “detecting LMOs”, suggesting that the mere presence of LMOs are adverse effects. It is advised to start this section with a listing of the various uses of monitoring, and to stick to monitoring changes.
Another issue that hinders the practical use of this section is that the distinction between “case specific” monitoring and “general monitoring” is introduced, but then keeps hanging in the air. It should be made clear that general monitoring has nothing to do with LMOs, is protection goal driven and has very little – if any – potential to establish causality.
To take away this confusion, the text should make clear that as of “Development Of A Monitoring Plan” is referring to case specific monitoring. It would probably be best to move the general monitoring to a footnote, to keep the flow of the text.

Q73: This section of the Guidance is useful or has utility.2

(no label) — Disagree

Q74: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:

See above

Q75: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) — Disagree

Q76: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:

The introduction of general monitoring is not something that appears in nor follows form the Protocol itself.

Q77: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label) — Strongly Disagree

Q78: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q79: Here you may provide further details to explain your answers in evaluating this section of the Guidance:	*Respondent skipped this question*

PAGE 17

Q80: Would you like to submit an evaluation of the following section of the Guidance: Background Documents	No

PAGE 18

Q81: This section of the Guidance is practical.1	*Respondent skipped this question*
Q82: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
Q83: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
Q84: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*

PAGE 19

Q85: **Please use the space below if you wish to provide additional feedback regarding the testing of the Guidance on Risk Assessment of Living Modified Organisms:**

PRRI warmly welcomes the MOP's request that the current guidance be tested for parameters as usefulness, practicality and consistency, and PRRI welcomes the Secretariat's approach of an online questionnaire in combination with the possibility of producing a paper version of the questionnaire.
Two things appeared challenging in filling in this questionnaire:
1) using real life dossiers: irrespective of the case taken, none of this guidance is specific enough to help identify in which cases certain points to consider would be relevant, and how those points could be answered.
2) Providing text proposals for specific lines in the document: given that the concerns expressed above often referred to matters that were pervasive throughout the document, it is not possible to provide specific comments at specific lines.